IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL SRL, and ORTHO-MCNEIL, INC.,	)	
Plaintiffs,	)	C.A. No. 07-255-JJF
v.	)	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	**REDACTED PUBLIC VERSION**
Defendants.	)	

DEFENDANTS' REPLY CLAIM CONSTRUCTION BRIEF

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INTRODUCTION

Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. ("Par") reply to Plaintiffs' opening brief on claim construction for the '887 and the '430 patents. Par's proposed claim constructions are based on the plain meaning of the disputed terms as understood by one of ordinary skill in the art and are supported by the intrinsic record. Plaintiffs' proposed constructions stray from what a person of ordinary skill would understand and, in most instances, fail to further clarify the disputed terms.

I. "Therapeutic Effect"

Par's Proposed Construction[1]	Plaintiffs' Proposed Construction[2]
The controlled release oral pharmaceutical preparation must produce analgesic efficacy in human patients experiencing pain as demonstrated by scientifically valid placebo-controlled clinical evidence.	Effective for the treatment of one or more clinical conditions, e.g., pain.

Plaintiffs' proposed construction conspicuously avoids what a person of ordinary skill in the art of pain management would understand this term to mean in the appropriate context. Their definition simply does not go far enough and is not much more than a restatement of the term. This is not the correct approach here given the complexities of defining "therapeutic effect" faced and understood by persons of ordinary skill in the relevant 1993-1994 time period. Par's experts, Dr. Stephan Grond and Dr. Michael Weinberger — prominent leaders in the field of pain medicine — explain with reference to the intrinsic evidence as well as contemporary references in the art why a person of ordinary skill in 1993-1994 would understand therapeutic effect consistent with Par's proposed construction.

[1] Colletti Decl. Ex. E.

[2] Colletti Decl. Ex. F.

Par's proposed construction is the plain meaning as determined from the perspective of a person of ordinary skill in the art. *Housey Pharms., Inc. v. AstraZeneca UK Ltd.*, 366 F.3d 1348, 1352 (Fed. Cir. 2004); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). It is supported by the intrinsic record. Nothing in the intrinsic or extrinsic record is inconsistent with Par's proposed construction.

The relevant art for the "therapeutic effect" of tramadol, an analgesic, is the art of pain management. (Colletti Decl. Ex. A: '887 patent, col. 1, ll. 10-12).[3] One of ordinary skill in the practice of pain management would generally be a person with a medical degree and a completed residency in a field that treats pain, such as anesthesiology, neurology, oncology, orthopedics and surgery. (Grond Decl. ¶ 12). A person with a formulation degree is not one of ordinary skill in the practice of pain management.

Evaluating or defining a "therapeutic effect" for a pain medication such as tramadol was understood in the relevant time period to be complicated by the placebo effect, by the necessarily subjective nature of defining pain and analgesia, and by the complex pharmacology of tramadol. Accordingly, a new tramadol sustained release product could not be defined as providing a therapeutic effect, let alone a therapeutic effect for a specific time period, without certain accepted studies. Indeed, one of ordinary skill would have understood in the 1993-1994 time frame a "therapeutic effect" of tramadol to mean analgesic efficacy that is shown to exist in human patients suffering from pain in scientifically valid studies that take into account the placebo effect. (Grond Decl. ¶ 13). The term "therapeutic" implies the treatment of a patient suffering from a clinical condition, such as pain. (Grond Decl. ¶ 14). And the "therapeutic

[3] The Declaration of Robert E. Colletti (D.I. 163) and the Declaration of Michael L. Weinberger, M.D. (D.I. 162) were submitted in conjunction with Par's Opening Brief. Reference is made to the exhibits attached to these declarations throughout this Reply.

effect" of tramadol is analgesia in patients suffering from pain, which is a complex and subjective experience that is caused by different physical, psychological and social mechanisms that affect the patient. (Grond Decl. ¶¶ 14-22). Therefore, the "therapeutic effect" of tramadol can only be determined in patients experiencing pain and not in healthy subjects who are pain-free or experience induced pain. (Grond Decl. ¶¶ 14, 20-22).

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Furthermore, a person of ordinary skill would have understood in the 1993-1994 time frame (and today would still understand) that a claim of a "therapeutic effect" of tramadol would have been shown by a scientifically valid study. (Grond Decl. ¶ 23). Most critically, this requires the use of an appropriate control that takes into account the substantial placebo effect that was known in the 1993-1994 time frame. (Grond Decl. ¶ 23). Indeed, Dr. Grond cites and attaches contemporary references in the art from the 1993-1994 time period to demonstrate that the substantial impact of the placebo effect on the evaluation of therapeutic effect for pain medication was understood at that time. (Grond Decl. ¶ 23, citing Turner, J.A. et al. (1994) "The Importance of Placebo Effects in Pain Treatment and Research," JAMA 271(20): 1609-1614) ("Turner (1994)"); Wall, P.D. (1993) "Pain and the placebo response," Ciba Foundation Symposium 174:187-211 ("Wall (1993)")). A placebo effect is an effect caused only by a patient's belief that, for example, the drug being studied is effective but not by the actual pharmacological effect of the drug. (Grond Decl. ¶ 24). The placebo effect varies greatly and

would have been understood in the early 1990's to be present in greater than one-third of patients treated with a placebo. (Grond Decl. ¶ 24).

Plaintiffs criticize Par's proposed construction of therapeutic effect by claiming that it seeks to import limitations relating to FDA approval criterion. Par does no such thing and indeed makes no reference to any such criterion. Instead, Par's proposed construction properly acknowledges the complexities of the pain management context and sets forth what a person of ordinary skill would recognize, understand and define as a "therapeutic effect." "[T]he line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms." *Phillips*, 415 F.3d at 1323. In contrast, Plaintiffs' proposed definition fails to account for the placebo effect or the context of the claimed invention.

Plaintiffs ignore the relevant context and what would have been known and needed to define a "therapeutic effect" for a pain medication in 1993-1994. Unlike Par, Plaintiffs submit declarations from individuals who are not clinicians. Their formulation expert, Dr. Davies, appears to rely on references to studies in the patents that involve no evaluation of pain in human patients as support. These studies concern the measurement of pharmacokinetic parameters (i.e., blood levels) in healthy patients with no measure of pain or analgesia and *in vitro* dissolution ranges (*i.e.*, "test tube" measurements of dissolution). (Pls.' Br. at 13; Grond Decl. ¶ 29). But such pharmacokinetic parameters, let alone *in vitro* dissolution results, cannot be used to determine tramadol's analgesic effect because there is no established or useful relationship between blood levels and pain relief for tramadol. (Grond Decl. ¶ 30). Several studies in postoperative pain have demonstrated a great inter- and intraindividual variability of blood concentrations and could not fix narrow analgesic threshold concentrations. (Grond Decl. ¶ 31).

For tramadol, interpretation of the relationship between blood concentrations and therapeutic effect is especially difficult because of: (i) interactions among the two enantiomers of tramadol and its active metabolites; and (ii) a delay of effect resulting from transport between blood and the central nervous system. (Grond Decl. ¶¶ 32-38).[4] Accordingly, the determination of a minimum effective concentration for the analgesic effect of tramadol is not possible because no quantitative data were available for the roles of the two enantiomers of tramadol or its primary active metabolite. (Grond Decl. ¶ 37).

In vitro dissolution profiles are even further removed from any evaluation of therapeutic effect than pharmacokinetic studies. (Grond Decl. ¶ 39). For the same reasons why pharmacokinetic studies are not a basis to show a therapeutic effect, *in vitro* dissolution profiles are no measure of a therapeutic effect. (Grond Decl. ¶ 40). In addition, *in vitro* dissolution profiles are merely one parameter of potential absorption (a pharmacokinetic parameter) of an active substance and absorption is influenced by a variety of other factors. (Grond Decl. ¶ 41). Indeed, the patentees themselves stated during prosecution of the '430 patent that "in-vitro dissolution ranges cannot predict in-vivo results." (Colletti Decl. Ex. D: '430 file history at PAR046790). Accordingly, as with pharmacokinetic parameters, *in vitro* dissolution ranges cannot be used to determine a therapeutic effect.

Par's proposed construction is proper because it is how one of ordinary skill in the practice of pain management would understand the term "therapeutic effect" and it is supported by the intrinsic record.

[4] Tramadol's analgesic effect was understood to be caused by at least three different "drugs", the two enantiomers of tramadol ((+)- and (-)-tramadol) and metabolite (+)-M1, via at least three distinct mechanisms. (Grond Decl. ¶¶ 31-33). And so no study of blood levels of tramadol would necessarily provide information on the level of the tramadol enantiomers or metabolite (+)-M1 at their site of action, the central nervous system.

A. "Therapeutic Effect For About 24 Hours After Oral Administration"

Par's Proposed Construction[5]	Plaintiffs' Proposed Construction[6]
The controlled release oral pharmaceutical preparation must produce analgesic efficacy in human patients experiencing pain as demonstrated by scientifically valid placebo-controlled clinical evidence and subsequent to oral administration of a dose of the preparation the analgesic efficacy in the patients must last for a period of about 24 hours from the time of onset of action.	Effective for the treatment of one or more clinical conditions, e.g., pain. (Plain and ordinary meaning; no construction necessary for "for at least about 24 hours" and "for about 24 hours after oral administration").

Par's proposed construction is the plain meaning as determined from the perspective of a person of ordinary skill in the art. A person of ordinary skill would have expected in the 1993-1994 time frame (and today would still expect) that a claim of a "therapeutic effect" "for at least about 24 hours" or "for about 24 hours after oral administration" would have been measured at regular intervals during a period of about 24 hours. (Grond Decl. ¶ 26). One of ordinary skill would have also understood in the 1993-1994 time frame (and today would still understand) that the duration of action for pain medicine is measured from the time when the analgesic effect of the medicine separates from placebo, i.e., onset of action. (Weinberger Decl. ¶ 22). Plaintiffs' proposed definition fails to account for the onset of action. Accordingly, Par's proposed construction does not seek to add any limitations to the phrase "therapeutic effect for about 24 hours after oral administration" or "therapeutic effect for about 24 hours after oral administration."

Further, Par's proposed construction reflects the reality that a drug that is administered once-a-day does not necessarily equate with a drug that is effective for the entire day.

[5] Colletti Decl. Ex. E.

[6] Colletti Decl. Ex. F.

(Weinberger Decl. ¶ 23). Many factors other than therapeutic effect can influence the dosing regimen for a drug, such as safety concerns like adverse events and toxicity that may limit dosing frequency regardless of the duration of effect. (Weinberger Decl. ¶ 23). Moreover, the patentees used the phrase "suitable for dosing every 24 hours" as a separate and distinct recitation from the phrase "therapeutic effect for about 24 hours after oral administration" in the claims of the '887 patent.[7]

As a matter of law, these different phrases must have different meanings.[8] *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1373 (Fed. Cir. 2004); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 111, 1119-20 (Fed. Cir. 2004); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1579 (Fed. Cir. 1996). And even Plaintiffs agree, stating that "[i]t is presumed that different words in a claim mean different things." (Pls.' Br. at 20). Accordingly, the phrases have different meanings. The phrase "suitable for dosing every 24 hours" has its ordinarily and customary meaning of "once-a-day dosing or administration," while "therapeutic effect for about 24 hours after oral administration" focuses on the duration of the therapeutic effect. (Colletti Decl. Ex. A: '887 patent, *compare* col. 2, ll. 9-10, 24, col. 3, ll. 5-6 with claims 1, 13, 19 and with col. 1, l. 24).

Par's proposed construction is proper because it is how one of ordinary skill in the practice of pain management would understand the phrase "therapeutic effect for about 24 hours after oral administration."

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[7] Because the '430 patent has the same specification as the '887 patent, the phrase "therapeutic effect for at least about 24 hours" should be construed in the same manner. *Biovail Corp. Int'l v. Andrx Corp.*, 239 F.3d 1297, 1301 (Fed. Cir. 2001).

[8] A patentee has "every incentive to exercise care in characterizing the scope of its invention." *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340,1350 (Fed. Cir. 2004).

II. "Matrix"

Par's Proposed Construction of "Matrix"[9]	Plaintiffs' Proposed Construction of "Matrix"[10]
A system wherein a drug is incorporated into a polymer(s) structure by either particle or molecular dispersion, wherein the former is a suspension of drug particles homogenously distributed in the polymer(s) structure and in the latter drug molecules are dissolved in the polymer, and wherein drug release occurs by diffusion through and/or erosion of the polymer structure.	A pharmaceutical preparation that incorporates the active ingredient dispersed within a solid dosage form.

Par's proposed construction is the plain meaning as understood by one of ordinary skill in the art of controlled release pharmaceutical preparations at the time the '430 patent was filed.[11] (Colletti Decl. Ex. S: Qiu and Guohua Zhang, *Research and Development Aspects of Oral Controlled-Release Dosage Forms*, in HANDBOOK OF PHARMACEUTICAL CONTROLLED RELEASE TECHNOLOGY, 465, 466-67 (Donald L. Wise ed., 2000)).

Plaintiffs' assertion that Par seeks to "limit" the term "matrix" to polymer structures is flawed.[12] (Pls.' Br. at 16). Par's proposed construction of the term "matrix" includes both a "normal release" matrix, as well as a "controlled release" matrix. Contrary to Plaintiffs' assertion, the use of the term "polymer" in Par's proposed construction does not exclude a "normal release" matrix. The portion of the specification that Plaintiffs cite as describing embodiments of "normal release" matrices in fact describes illustrative suitable materials as "water soluble polymers... or water insoluble polymers." (Colletti Decl. Ex. A: '887 patent, col. 4, ll. 24-44 (emphasis added)). Accordingly, Par's proposed construction is consistent with the

[9] Colletti Decl. Ex. E.

[10] Colletti Decl. Ex. F.

[11] The term "matrix" is recited only in the independent claim, claim 1, of the '430 patent, but not in the claims of the '887 patent.

[12] Plaintiffs' argument is a non-sequitur. (*See* Pls.' Br. at 15-16).

intrinsic record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 1321 (Fed. Cir. 2005) (the construction that aligns with the written description is the correct construction; extrinsic evidence should be considered in the context of the intrinsic evidence where applicable).

Further, exemplary materials in the '887 patent and the '430 patent include (i) alkylcelluloses, such as ethyl cellulose; (ii) digestible, long chain hydrocarbons, such as waxes and fatty alcohols; and (iii) polyalkylene glycols, such as polyethylene glycol. These are the same materials that Plaintiffs assert are incorporated in their proposed construction. (Pls' Br. at 15; *compare with* Colletti Decl. Ex. 1: '887 patent, col. 3, ll. 48-67). All of these materials were known by one of ordinary skill at the time the '430 patent was filed as polymers. (Supplemental Declaration of Robert E. Colletti. Ex. 1 at 443, Table 1, filed contemporaneously herewith).

Par's proposed construction is proper because it is supported by the extrinsic record and is consistent with the limited intrinsic record. In contrast, Plaintiffs' proposed construction is redundant with the claim term "substrate." (Def. Br. at 20).

A. "Normal Release Matrix"

Par's Proposed Construction[13]	Plaintiffs' Proposed Construction[14]
A matrix that does not slow the release of the active ingredient.	A matrix that does not substantially slow the release of the active ingredient.

Par's proposed construction of the phrase "normal release matrix" strictly applies the converse of the patentee's own definition of a "controlled release preparation." A "controlled release preparation" is defined by the inventors in the specification as one that "achieves slow release of a drug." (Colletti Decl. Ex. B: '430 patent, col. 1, ll. 40-43).

[13] Colletti Decl. Ex. G.

[14] Colletti Decl. Ex. F.

Plaintiffs' proposed construction is improper. It seeks to import a limitation that is not supported in the specification (*i.e.*, "substantially") and it is contrary to the inventors' own language, *viz.* "controlled release preparation." Because Par's proposed construction aligns with the written description, it is the proper construction. *Phillips*, 415 F.3d at 1316.

III. "Pharmaceutically Effective Amount of Tramadol Or a Salt Thereof"

Par's Proposed Construction[15]	Plaintiffs' Proposed Construction[16]
An amount of tramadol or its salt contained in the substrate or the normal release matrix to achieve a therapeutic effect.	An amount of tramadol or its salt sufficient to provide at least some analgesia.

Par's proposed construction comports with the intrinsic record and the inventors' own use of the phrase "pharmaceutically effective."[17] The synonymous treatment of the phrases "pharmaceutically effective" and "therapeutically effective" by the patentees is most telling.[18] (*Compare, e.g.*, claim 1 of the '887 patent (Colletti Decl. Ex. A) with claim 1 of the '430 patent (Colletti Decl. Ex. B)).

[15] Colletti Decl. Ex. G.

[16] Colletti Decl. Ex. F

[17] This phrase is recited in the claims of the '887 patent, but not in the claims of the '430 patent.

[18] The patentees also used the phrase "analgesically effective" interchangeably with the phrases "pharmaceutically effective" and "therapeutically effective" because analgesia is the pharmaceutical or therapeutic effect of tramadol. (Colletti Decl. Ex. A, '887 patent, col. 3, l. 28; col. 1, ll. 10-12).

'887 patent, claim 1	'430 patent, claim 1
1. A controlled release oral pharmaceutical preparation suitable for dosing every 24 hours comprising a substrate comprising a pharmaceutically effective amount of tramadol or a salt thereof; said substrate coated with a controlled release coating; said preparation having a dissolution rate in vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0,1 N [sic 0.1 N] hydrochloric acid at 37° C. and using UV detection at 270 nm, between 0 and 50% tramadol released after 1 hour; between 0 and 75% tramadol released after 2 hours; between 3 and 95% tramadol released after 4 hours; between 10 and 100% tramadol released after 8 hours; between 20 and 100% tramadol released after 12 hours; between 30 and 100% tramadol released after 16 hours; between 50 and 100% tramadol released after 24 hours; and greater than 80% tramadol released after 36 hours, by weight, said preparation providing a therapeutic effect for about 24 hours after oral administration.	1. A solid controlled release oral dosage form, comprising, a therapeutically effective amount of tramadol or a pharmaceutically acceptable salt thereof incorporated into a normal release matrix, said matrix overcoated with a controlled release coating comprising a polymethacrylate or a water insoluble cellulose, said dosage form providing a therapeutic effect for at least about 24 hours.

Claim 1 of the '887 patent uses the phrase "pharmaceutically effective" in the context of tramadol contained in a substrate or a tablet, and claim 1 of the '430 patent uses the phrase "therapeutically effective" in the context of tramadol contained in a normal release matrix.

Plaintiffs' proposed construction is improper as it is contrary to the intrinsic record and is not supported by the specification. Plaintiffs would have the Court treat "therapeutic effect" and "pharmaceutically effective" as different despite the patentees' clear intent. Plaintiffs' disingenuous attempt to distinguish between these two terms is apparent when comparing their proposed constructions.

Plaintiffs' Proposed Construction of "Pharmaceutically Effective"[19]	Plaintiffs' Proposed Construction of "Therapeutic Effect"[20]
An amount of tramadol or its salt sufficient to provide at least some analgesia.	Effective for the treatment of one or more clinical conditions, e.g., pain.

Given that the pharmaceutical or therapeutic effect of tramadol is analgesia (pain relief), there is no meaningful difference between Plaintiffs' proposed construction for these terms—other than the vague and unsupported qualifying term "some." (Colletti Decl. Ex. A, '887 patent, col. 1, ll. 10-12). Plaintiffs' proposed construction is contrary to the intrinsic record and to the plain meaning of these terms. In contrast, Par's proposed construction is true to the claim language. *Phillips*, 415 F.3d 1303 at 1316.

CONCLUSION

For the foregoing reasons, Par respectfully requests that the Court enter an order construing the terms and phrases of the '887 patent and the '430 patent as proposed by Par.

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[19] Colletti Decl. Ex. F.

[20] Colletti Decl. Ex. F.

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IN THE UNITED STATES DISTRICT COURT
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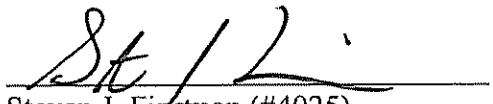

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